DISCUSSION OF THE AMENDMENT

Due to the length of the specification herein, Applicants will cite to the paragraph number of the published patent application (PG Pub) of the present application, i.e., US 2006/0135469, when discussing the application description, both in this section and in the Remarks section, *infra*, rather than to page and line of the specification as filed.

Claim 1 has been amended by inserting that liquid (A) may also contain hyaluronic acid *per se*, and thus adding that the acid and the ester derivative are alternatively a hyaluronic acid component. Claim 1 has been further amended by replacing the term "characterized in that it" with --which--.

Claim 9 has been amended to recite that the pharmaceutically acceptable lubricant is present.

Remaining amendments have been made to be consistent with the above-discussed amendment to Claim 1, to remove improper multiple dependencies, and to delete redundant language.

No new matter is believed to have been added by the above amendment. Claims 1-11 remain pending in the application.

REMARKS

The rejection of Claims 1-11 under 35 U.S.C. § 103(a) as unpatentable over the Merck Index (O'Neil et al) in view of the article *Pharmaceutical Necessities* in Remington's Pharmaceutical Sciences (Swinyard et al), is respectfully traversed.

As recited in above-amended Claim 1, an embodiment of the present invention is a separate type medical material, which comprises liquid (A) which is an aqueous solution containing a hyaluronic acid component which is hyaluronic acid or a hyaluronic acid ester derivative, and which component is buffered to a pH of from 4.5 to 6.5, and liquid (B) which is an aqueous solution having such a buffering power that when it is mixed with the liquid (A), the mixed liquid has a pH within a range of from 6.8 to 7.8, and the liquid (A) and the liquid (B) are kept separately from each other before administration and administered as mixed.

The Examiner holds that it would have been obvious to combine the disclosures of O'Neil et al and Swinyard et al "as a part of the process of routine experimentation to optimize a method of treatment" disclosed in O'Neil et al.

In reply, and contrary to the holding by the Examiner, the present invention is not simply the separate combination of a hyaluronic acid component and a buffer. Rather, as above-recited, liquid (A) is pH-adjusted to a pH of from 4.5 to 6.5, and liquid (B) has such buffering power that when it is mixed with liquid (A) the pH is between 6.8 and 7.8. The present invention is based, at least in part, on Applicants' discovery that the hyaluronic acid component has a higher stability under a weakly acidic condition in a pH region of from 4.5 to 6.5, as disclosed in the specification at paragraph [0013]. There is no disclosure or suggestion in either reference to pH-adjust the hyaluronic acid component, prior to combining with another liquid for adjustment of the final pH, just prior to administration. Accordingly, it is respectfully requested that this rejection be withdrawn.

The rejection of Claims 1-11 under 35 U.S.C. § 112, first paragraph, while being enabled for the administration of hyaluronic acid in the presence of a buffer, does not reasonably provide enablement for making or using any hyaluronic acid ester derivative, is respectfully traversed. Applicable hyaluronic acid ester derivatives are described in the specification at [0038]-[0040]. See also paragraphs [0007]-[0009]. Based on the specification as a whole, it is clear that the present invention is not limited to particular hyaluronic acid ester derivatives, but, in effect, is inclusive of all such derivatives having the capability of treating arthropathy.

The Examiner's rationale is not in accordance with law. As the CCPA has stated:

> The board suggests that the claims "would read on any liquid or solid (liquefiable under the reaction conditions) since all liquids tend to agglomerate (e.g., water, mercury, oils, etc.)." However, we disposed of a similar argument in *In re Geerdes*, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974), thus:
>
> > [W]e cannot agree with the board's determination that the claims are inclusive of materials which would not apparently be operative in the claimed process. *** Having stated the objective *** together with the process steps, use of materials which might prevent achievement of the objective *** can hardly be said to be within the scope of the claims.
>
> For all practical purposes, the board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts." See *In re Fuetterer*, 319 F.2d 259, 265, 138 USPQ 217, 223 (1963).

In re Goffe, 542 F.2d 564, 191 USPQ 429, 431 (CCPA 1976).

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The rejection of Claims 1-11 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. All improper multiple dependency and lack of proper antecedent bases have been eliminated. Regarding the term "hyaluronic acid ester derivative" and "self-crosslinking

hyaluronic acid", such terms are well understood in this art, as discussed above with regard to the rejection under 35 U.S.C. § 112, first paragraph. Similarly, the terms "medicine" and "pharmaceutically acceptable lubricant" in Claim 5, as well as "phospholipid" in Claim 9, are suitably supported in the specification at paragraphs [0055] and [0056]. Clearly, one skilled in the art would understand the metes and bounds of such materials. The remaining rejections would now appear to be moot.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The objection to the declaration is respectfully traversed. According to 37 C.F.R. § 1.63(c), the mailing address must be identified in the oath or declaration, only if it is not supplied on an Application Data Sheet (ADS) in accordance with 37 C.F.R. § 1.76. Such information is provided in the ADS of record herein, filed February 16, 2005. Accordingly, it is respectfully requested that the requirement of a new oath or declaration be withdrawn.

All of the presently-pending claims in this application are now believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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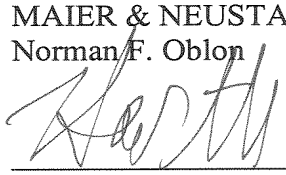

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